

**DEPARTMENT OF COMMERCE**

**Patent and Trademark Office**

**37 CFR Part 1**

**[Docket No. PTO-P-2021-0061]**

**RIN 0651-AD59**

**Establishing Permanent Electronic Filing for Patent Term Extension Applications**

**AGENCY:** United States Patent and Trademark Office, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** To further advance the United States Patent and Trademark Office's (USPTO or Office) information technology strategy of achieving complete beginning-to-end electronic processing of patent-related submissions, the USPTO is revising the Rules of Practice in Patent Cases to require that patent term extension (PTE) applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system (Patent Center or EFS-Web). The rule changes reduce the administrative burden on PTE applicants and improve administrative efficiency by facilitating electronic file management, optimizing workflow processes, and reducing processing errors.

**DATES:** This rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**FOR FURTHER INFORMATION CONTACT:** Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-0909; or Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7728. You can also send inquiries to *patentpractice@uspto.gov*.

**SUPPLEMENTARY INFORMATION:** PTE under 35 U.S.C. 156 enables the owners of patents that claim certain human drug products, medical device products, animal drug

products, veterinary biological products, or food or color additive products to restore to the terms of those patents some of the time lost while awaiting premarket government approval for the products from a regulatory agency. *See, e.g.*, section 2750 of the Manual of Patent Examining Procedure (MPEP, Ninth Edition, R-10.2019). The USPTO administers 35 U.S.C. 156 in partnership with the relevant regulatory agencies (i.e., the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA)). As part of its administration, the USPTO sends to the relevant agency a copy of any initial submission for PTE that the USPTO receives (i.e., a copy of any PTE application under 35 U.S.C. 156(d)(1) and 37 CFR 1.740 or any interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790).

Prior to the COVID-19 pandemic, the USPTO prohibited the electronic filing of initial submissions for PTE. *See* section B2 of the Legal Framework for Patent Electronic System, available at [www.uspto.gov/patents/apply/filing-online/legal-framework-efs-web](http://www.uspto.gov/patents/apply/filing-online/legal-framework-efs-web) and section 502.05(I)(B)(2) of the MPEP. Requiring initial PTE submissions, which often comprise hundreds of pages to be physically filed in triplicate under 37 CFR 1.740(b), was viewed as the most effective way to minimize processing errors.

Due to the workplace changes caused by the COVID-19 pandemic, the USPTO waived its prohibition on the electronic filing of initial submissions for PTE and the triplicate copy requirements in 37 CFR 1.740(b) and 1.790(b). *See* Relief Available to Patentees in View of the COVID-19 Outbreak for Submission of Initial Patent Term Extension Applications Filed Pursuant to 35 U.S.C. 156, 1475 Off. Gaz. Pat. Office 234 (June 23, 2020). The waiver did not impact related follow-on submissions to the USPTO, which were already permitted to be filed electronically prior to the pandemic.

Through informal feedback, stakeholders have thus far communicated unanimous support for electronic filing of initial PTE submissions. Additionally, the USPTO and its partner agencies have successfully implemented a system by which the USPTO electronically transmits a copy

of any initial submission for PTE to the relevant agency. The new system has not caused any processing errors.

The USPTO is revising its rules of practice to require that PTE applications, interim PTE applications, and any related submissions to the USPTO be submitted electronically via the USPTO patent electronic filing system. The changes are designed to streamline the filing of PTE applications and related documents and minimize paper handling. As has been the case since the June 2020 implementation of the electronic filing waiver, PTE applications will be viewable in the USPTO patent electronic viewing systems (Patent Center or the private Patent Application Information Retrieval (PAIR) system) immediately upon filing. The changes permit the USPTO to more efficiently allocate the personnel and physical space it currently deploys for the handling of physical copies of PTE submissions.

Due to the revised rules, PTE applicants must use the correct document description to ensure that USPTO personnel are timely apprised of electronic submissions. “Patent Term Extension Application Under 35 USC 156” (document code TERM.REQ) is the correct document description for a PTE application under 35 U.S.C. 156(d)(1) and 37 CFR 1.740, and “Interim Patent Term Extension Application Under 35 USC 156(d)(5)” (document code TERM.REQ.ITM) is the correct document description for an interim PTE application under 35 U.S.C. 156(d)(5) and 37 CFR 1.790. The USPTO patent electronic filing system also includes the document descriptions “Interim Patent Term Extension Request Under 35 USC 156(e)(2)” (document code TERM.REQ.E2) for requests for interim extension of the patent term under 35 U.S.C. 156(e)(2) and 37 CFR 1.760, and “Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application” (document code TERM.PTE.DIS) for disclosures to the USPTO under 37 CFR 1.765.

Note that the USPTO changed the document code corresponding to the document description “Disclosure Under 37 CFR 1.765 in a Patent Term Extension Application” to TERM.PTE.DIS from the document code TERM.DISCL, which was announced in the notice of proposed rulemaking published on May 6, 2022, at 87 FR 27043. The document code

TERM.DISCL was being erroneously used by filers for the submissions of terminal disclaimers. PTE applicants are reminded that, when multiple PTE applications are filed for different patents based on the same regulatory review period, it is incumbent upon the PTE applicants to inform the USPTO of the various PTE applications, pursuant to 37 CFR 1.740(a)(13) and 37 CFR 1.765. *See also* section 2761 of the MPEP.

The USPTO patent electronic filing system includes the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA) for limited powers of attorney and/or changes of correspondence address that are filed specifically for PTE applications. Although a power of attorney (POA) or limited POA is not required for a practitioner to prosecute a PTE application (practitioners may prosecute PTE applications by acting in a representative capacity pursuant to 37 CFR 1.34), the USPTO routinely receives limited POAs specifying that the power is limited to prosecution of the PTE application. A limited POA filed using the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA) will not be processed by the Office of Patent Application Processing (OPAP) and will not serve to change an existing power for the underlying patent or establish power for the underlying patent.

As for a change of the correspondence address that is filed specifically for a PTE application, the USPTO uses the 37 CFR 1.740(a)(15) address provided in an initial PTE or interim PTE application strictly for communications regarding the PTE application. If a PTE applicant subsequently wishes to change the 37 CFR 1.740(a)(15) address, the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA), should be used. A change of address filed using the document description, “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA) will not be processed by the OPAP and will not serve to change the correspondence address for the underlying patent. PTE applicants are

reminded to separately file a change of address with any other relevant regulatory agency to timely receive copies of correspondence from that agency.

PTE applicants are strongly encouraged to confirm that they have used the correct document description for any PTE submission, especially time-sensitive PTE submissions, such as interim PTE applications under 35 U.S.C. 156(d)(5) and 37 CFR 1.790 or requests for interim extension of the patent term under 35 U.S.C. 156(e)(2) and 37 CFR 1.760. Use of the correct document description may be verified by reviewing the EFS Acknowledgement Receipt (document code N417) issued for the submission. In addition, both the document description and code for a submission may be verified in the electronic application file. If a mistake is identified, PTE applicants should contact the Patent Electronic Business Center at 866-217-9197 or [EBC@uspto.gov](mailto:EBC@uspto.gov).

When electronically filing a PTE or interim PTE application, the PTE or interim PTE application, including all exhibits, attachments, or appendices, should be submitted as a single file. If the single file comprising the application and its exhibits, attachments, or appendices exceeds the upload limit of the USPTO patent electronic filing system, the file may be split into smaller files to permit uploading, but the number of separate files to be uploaded should be minimized. Additionally, when splitting a file into smaller files, the order of the exhibits, attachments, or appendices as mentioned in the application should be maintained, and a single exhibit, attachment, or appendix should not be split, if possible. The USPTO patent electronic filing system includes the document description, "Continuation of Patent Term Extension Application" (document code PTE.APPENDIX), to be used for any exhibit, attachment, or appendix to a PTE or interim PTE application that is filed separately from the application.

In the limited circumstance when the USPTO patent electronic filing system is unavailable during an unscheduled outage and a PTE application, interim PTE application, or any related submission to the USPTO cannot be filed electronically, the USPTO may, on its own initiative, waive the electronic filing requirement under 37 CFR 1.740(b) for the application

or submission to enable the application or submission to be filed by hand-delivery to the USPTO, or via the “Priority Mail Express<sup>®</sup>” service of the United States Postal Service in accordance with 37 CFR 1.10, and be entitled to a filing date. When submitting by hand-delivery or “Priority Mail Express<sup>®</sup>,” the PTE applicant must provide an explanation of the unavailability of the USPTO patent electronic filing system.

The filing fee under 37 CFR 1.20(j) is not a filing date requirement under 37 CFR 1.741(a). PTE applications and interim PTE applications will receive a filing date without the filing fee. If the USPTO patent electronic filing system is available, but the fee payment component of the USPTO patent electronic filing system is not accepting payment, PTE applicants may include an authorization to charge a deposit account as an acceptable form of payment (see 37 CFR 1.25(b)) or they may delay payment to a later time. If payment has not been made by the time the USPTO processes the application, the USPTO will notify the PTE applicant to pay the 37 CFR 1.20(j) filing fee, in accordance with 37 CFR 1.740(c).

### **Discussion of Specific Rules**

The following is a discussion of the amendments to 37 CFR part 1.

*Section 1.740:* Section 1.740(a)(15) is amended to require the provision of an email address of the person to whom inquiries and correspondence related to the PTE application are to be directed. The USPTO has found that the availability of an email address facilitates contact with the PTE applicant’s representative.

Section 1.740(b) is amended to require that PTE applications under § 1.740, and any related submissions to the USPTO, be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. Submissions to the USPTO related to PTE applications under § 1.740 include any related follow-on documents that must be submitted to the USPTO, such as corrections of informalities under § 1.740(c), petitions requesting review of incomplete filings or review of an accorded filing date under § 1.741(b), requests for reconsideration of notices of final determination and responses to requirements for information under § 1.750, requests for 35 U.S.C. 156(e)(2) interim

extensions under § 1.760, disclosures to the USPTO under § 1.765, express withdrawals under § 1.770, and replies to requests to identify the holder of an approval under § 1.785(d). PTE-related submissions to the FDA or the USDA, such as disclosures to the Secretary of Health and Human Services or the Secretary of Agriculture under § 1.765, should continue to be filed directly with the relevant agency. This final rule removes from § 1.740(b) the requirement to file each PTE application in triplicate.

*Section 1.741:* Section 1.741(a) is amended to provide that the filing date of a PTE application is the date on which a complete PTE application is either received in the USPTO via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). In view of the requirement to file PTE applications via the USPTO patent electronic filing system, this final rule removes from § 1.741(a) the provision that provided that the filing date of a PTE application may be the date on which a complete application is filed pursuant to the physical mailing or facsimile transmission procedures set forth in §§ 1.8(a)(1)(i)(A) or (B) or 1.10.

Section 1.770 is amended to remove the requirement to file duplicates of express declarations of withdrawal of PTE applications. The requirement is no longer needed in view of the requirement to file submissions related to PTE applications via the USPTO patent electronic filing system.

*Section 1.790:* Section 1.790(a) is amended to clarify that the referenced paragraphs are paragraphs of 35 U.S.C. 156(g). Additionally, the time periods previously in § 1.790(a) for filing initial and subsequent applications for interim extension are moved to new paragraphs (c)(1) and (d)(1), respectively, of this section.

Section 1.790(b) is amended to require any application for interim extension under this section (i.e., both initial and subsequent interim extension applications) to be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements. This final rule moves the provisions regarding a complete application for interim extension from § 1.790(b) to new paragraph (c)(2) of this section.

Section 1.790(c) is amended to provide the requirements for complete initial applications for interim extension. Newly added § 1.790(c)(1) contains the time period for filing an initial interim extension application previously in § 1.790(a). It also requires a statement that the initial application is being submitted within the time period and an identification of the date of the last day on which the initial application could be submitted. Newly added § 1.790(c)(2) contains the provisions regarding a complete interim extension application previously in § 1.790(b). Paragraphs (a)(16) and (17) were removed from § 1.740 on September 8, 2000. Accordingly, the reference to § 1.740(a)(16) and (17) previously in § 1.790(b) is not carried over to § 1.790(c)(2). Newly added § 1.790(c)(3) requires a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product.

Newly added § 1.790(d) contains the requirements for subsequent interim extension applications. Newly added § 1.790(d)(1) contains the time period for filing each subsequent interim extension application previously in § 1.790(a). It also requires a statement that the subsequent application is being submitted within the time period and an identification of the date of the last day on which the subsequent application could be submitted. Newly added § 1.790(d)(2) contains provisions regarding the content of each subsequent interim extension application previously in § 1.790(c). Newly added § 1.790(d)(3) contains the requirement that an application contain a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed, which was previously in § 1.790(c).

### **Changes from the Proposed Rule**

This final rule removes a provision proposed in the May 6, 2022, notice of proposed rulemaking. Specifically, § 1.790(c)(3) does not include the proposed requirement to identify the application, petition, or notice that caused the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), to begin. The proposed requirement is unnecessary in view of the requirements set forth in

§ 1.740(a)(10), e.g., the requirement in § 1.740(a)(10)(i)(B) to provide the new drug application number for a patent claiming a human drug. A complete initial application for interim extension must meet the requirements set forth in § 1.740(a)(10) under newly added § 1.790(c)(2) (previously under § 1.790(b)).

### **Comments and Responses to Comments**

The May 6, 2022, notice of proposed rulemaking solicited public comments on the proposed amendments to 37 CFR part 1 being adopted in this final rule. The USPTO received written input from two commenters on the proposed rule. Summaries of the comments and the USPTO's responses to the written comments follow.

*Comment 1:* One comment noted that, because a limited POA document might be submitted as an exhibit to an initially-filed PTE application or initially-filed interim PTE application, either the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA) or the document description “Continuation of Patent Term Extension Application” (document code PTE.APPENDIX) might be used. The comment asked the USPTO to clarify that either would be acceptable for initial filings and that changes in power filed subsequent to the initial filings should use the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA).

*Response:* Yes, PTE applicants may continue to include limited POAs for PTE applications as part of an appendix document that is submitted using the document description “Continuation of Patent Term Extension Application” (document code PTE.APPENDIX). However, the USPTO prefers all limited POAs for PTE applications to be filed as a separate document using the document description “Limited POA and/or Change of Address for a Patent Term Extension Application” (document code PTE.POA). By doing so, the limited POA is more readily identifiable in the electronic file wrapper.

*Comment 2:* One comment expressed concern that electronic filing could significantly exacerbate the unauthorized filing of PTE applications by patent owners who are not the marketing applicant or its agent. The comment proposes that the USPTO address the issue by amending 37 CFR 1.740 to expressly require, in any PTE application where the patent owner is a different and unrelated entity from the marketing applicant, an authorization letter from the marketing applicant allowing the patent owner to rely on the regulatory review period activities of the marketing applicant. The comment further proposes that such an authorization letter would need to be submitted during the pendency of the PTE application.

*Response:* The USPTO understands the commenter's concern. However, the proposal is outside the scope of the current rulemaking. The USPTO will consider requiring an authorization letter in a future rulemaking.

*Comment 3:* One comment asked the USPTO to continue to allow the filing of trade secret, proprietary, and protective order material on paper in PTE applications using the procedures of MPEP sections 724.02 and 2760.

*Response:* The process for filing trade secret, proprietary, and/or protective order material on paper in PTE applications using the procedures of MPEP sections 724.02 and 2760 is not being changed by this final rule. If the USPTO receives a submission in accordance with the procedures of MPEP sections 724.02 and 2760, the USPTO will, on its own initiative, waive the electronic filing requirement under 37 CFR 1.740(b) for the submission.

*Comment 4:* One comment asked the USPTO to consider a provision that would allow a PTE applicant to submit a PTE application on paper if the USPTO's patent electronic filing system is not working.

*Response:* As stated earlier, in the limited circumstance when the USPTO patent electronic filing system is unavailable during an unscheduled outage, the USPTO may waive the electronic filing requirement under 37 CFR 1.740(b) for a PTE application, interim PTE application, or any related submission to the USPTO, if the application or submission is

accompanied by an explanation of the unavailability of the USPTO patent electronic filing system and requests waiver (a petition under 37 CFR 1.183 is not required).

*Comment 5:* One comment requested that the USPTO ensure that all PTE correspondence becomes part of the USPTO's electronic system that provides applicants with an email notification that a new document has been added to the electronic file wrapper.

*Response:* The USPTO understands the comment to be requesting that all USPTO communications issued with respect to a PTE application be included in the USPTO's e-Office Action program. See [www.uspto.gov/patents/apply/checking-application-status/e-office-action-program](http://www.uspto.gov/patents/apply/checking-application-status/e-office-action-program). The electronic notification system currently used by the USPTO for its e-Office Action program cannot accommodate communications issued with respect to a PTE application. If that changes, the USPTO will revisit the matter. In the interim, the USPTO will endeavor to notify the PTE applicant of any outgoing USPTO PTE correspondence via the email address provided under 37 CFR 1.740(a)(15).

## **Rulemaking Requirements**

***A. Administrative Procedure Act:*** The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. See *Bachow Commc'ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals are procedural where they do not change the substantive standard for reviewing claims); *Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive).

Prior notice and opportunity for public comment for the changes in this rulemaking were not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. See *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" (quoting

5 U.S.C. 553(b)(A))). However, the USPTO chose to seek public comment before implementing the rule to benefit from the public's input.

***B. Regulatory Flexibility Act:*** For the reasons set forth in this final rule, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this rule will not have a significant economic impact on a substantial number of small entities (see 5 U.S.C. 605(b)).

PTE, under 35 U.S.C. 156, is only available for patents that claim drug products, medical devices, food or color additives, or methods of using or manufacturing such products, devices, or additives. Approximately 100 PTE applications are filed annually, and they are typically filed by non-small entity pharmaceutical and medical device companies because of the expense required to develop and obtain marketing approval for such inventions.

The changes in this rule are procedural in nature and are not expected to result in significant costs to applicants. The rules of practice prior to this final rule already permitted follow-on documents related to PTE applications to be filed electronically. The USPTO estimates that approximately 99% of follow-on documents related to PTE applications were being filed electronically prior to this final rule. Accordingly, the rule change requiring follow-on documents related to PTE applications to be filed electronically should not cause a substantial change in practice or result in additional costs to PTE applicants. As for the rule change requiring PTE applications to be filed electronically, although this is a change in practice, stakeholders have unanimously communicated support for the USPTO's waiver of the prohibition against electronic filing of PTE applications as a result of the COVID-19 outbreak, and the rule change is not expected to result in any additional cost to applicants. Thus, this rule change requiring PTE applications to be filed electronically is not expected to negatively impact stakeholders' PTE practice.

The USPTO patent electronic filing system allows PTE applicants to file PTE documents through a standard web browser without downloading special software, changing

documentation preparation tools, or altering workflow processes. PTE applicants may create documents using the tools and processes that they already use, and then convert those documents into standard PDF files for submission through the USPTO's patent electronic filing system.

For these reasons, the changes will not have a significant economic impact on a substantial number of small entities.

***C. Executive Order 12866 (Regulatory Planning and Review):*** This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

***D. Executive Order 13563 (Improving Regulation and Regulatory Review):*** The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

***E. Executive Order 13132 (Federalism):*** This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

***F. Executive Order 13175 (Tribal Consultation):*** This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct

compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

***G. Executive Order 13211 (Energy Effects):*** This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

***H. Executive Order 12988 (Civil Justice Reform):*** This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

***I. Executive Order 13045 (Protection of Children):*** This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

***J. Executive Order 12630 (Taking of Private Property):*** This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

***K. Congressional Review Act:*** Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

***L. Unfunded Mandates Reform Act of 1995:*** The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

***M. National Environmental Policy Act of 1969:*** This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

***N. National Technology Transfer and Advancement Act of 1995:*** The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

***O. Paperwork Reduction Act of 1995:*** The Paperwork Reduction Act of 1995 requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the paperwork and other information collection burdens involved with this rulemaking have already been approved under the Office of Management and Budget (OMB) Control Number 0651–0020 (Patent Term Extension and Adjustment). However, 0651–0020 is being updated to reflect a net reduction in burden (time). Taking into consideration the removal of the requirement to file PTE applications in paper in triplicate and the additional requirements of newly added 37 CFR 1.790(c)(1) and (d)(1), the USPTO estimates that this information collection’s annual burden will decrease by a total of approximately 72 burden hours. This estimate is based on the response volumes associated with the most recent OMB submissions for this information collection.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject

to the requirements of the Paperwork Reduction Act unless that collection of information has a currently valid OMB control number.

***P. E-Government Act Compliance:*** The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to government information and services, and for other purposes.

## **List of Subjects in 37 CFR Part 1**

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, the USPTO amends 37 CFR part 1 as follows:

## **PART 1 - RULES OF PRACTICE IN PATENT CASES**

1. The authority citation for 37 CFR part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Amend § 1.740 by revising paragraphs (a)(15) and (b) to read as follows:

### **§ 1.740 Formal requirements for application for extension of patent term; correction of informalities.**

(a) \* \* \*

(15) The name, address, telephone number, and email address of the person to whom inquiries and correspondence related to the application for patent term extension are to be directed.

(b) The application under this section, and any related submissions to the Office, must be submitted using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

\* \* \* \* \*

3. Amend § 1.741 by revising paragraph (a) introductory text to read as follows:

**§ 1.741 Complete application given a filing date; petition procedure.**

(a) The filing date of an application for extension of a patent term is the date on which a complete application is received in the Office via the USPTO patent electronic filing system or filed pursuant to the procedure set forth in § 1.8(a)(1)(i)(C) and (a)(1)(ii). A complete application must include:

\* \* \* \* \*

4. Amend § 1.770 by revising the first sentence to read as follows:

**§ 1.770 Express withdrawal of application for extension of patent term.**

An application for extension of patent term may be expressly withdrawn before a determination is made pursuant to § 1.750 by filing in the Office a written declaration of withdrawal signed by the owner of record of the patent or its agent. \* \* \*

5. Revise § 1.790 to read as follows:

**§ 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).**

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) Any application for interim extension under this section must be filed using the USPTO patent electronic filing system in accordance with the USPTO patent electronic filing system requirements.

(c) Complete initial applications for interim extension under this section must:

(1) Be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire, and include a statement that the initial application is being submitted within the period and an identification of the date of the last day on which the initial application could be submitted;

(2) Include all of the information required for a formal application under § 1.740 and a complete application under § 1.741, except as follows:

(i) Paragraphs (a)(1), (2), (4), and (6) through (15) of §§ 1.740 and 1.741 shall be read in the context of a product currently undergoing regulatory review; and

(ii) Paragraphs (a)(3) and (5) of § 1.740 are not applicable to an application for interim extension under this section; and

(3) Include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has begun for the product that is the subject of the patent.

(d) Each subsequent application for interim extension:

(1) Must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension and include a statement that it is being submitted within the period and an identification of the date of the last day on which it could be submitted;

(2) May be limited in content to a request for a subsequent interim extension along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application; and

(3) Must include a statement that the applicable regulatory review period, described in 35 U.S.C. 156(g)(1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii), has not been completed.

**Katherine K. Vidal,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

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